REMARKS

In the Office Action dated August 15, 2006, claims 1-26 are pending, of which claims 7-10, 14-20, 23, 25 and 26 have been withdrawn from consideration as directed to non-elected subject matter. Claims 1-6, 21 and 22 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking enablement. Claims 1-3, 21 and 24 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 1, 3, 4, 6, 11, 21, 22 and 24 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by Iris et al., (U.S. Patent No. 6,403,309). Claims 2, 5 and 12 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Iris et al., as applied to claims 1, 3, 4, 6, 11, 21, 22 and 24 above, and further in view of Palo (U.S. Patent No. 6,556,296 B1). Claim 13 is rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Iris et al., as applied to claims 1, 3, 4, 6, 11, 21, 22 and 24 above, and further in view of Fujimiya et al., (U.S. Patent No. 5,190,632). The Examiner has also alleged that Applicants have not filed a certified copy of Japanese application No. 2000-087500.

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

In the first instance, Applicants respectfully submit that certified copies of all three priority documents were submitted on May 31, 2005, as evidenced by the stamped return post card from the Patent Office (copy attached).

In the Office Action, claims 1-6, 21 and 22 are rejected under 35 U.S.C. §112, first paragraph. The Examiner acknowledges that the specification is enabling for detecting a polymorphism in a test sample containing a polymorphism site by optically measuring and analyzing a change of a fluorescent dye at a plurality of time points when the test sample is a

DNA. However, the Examiner alleges that the specification does not reasonably provide enablement for detecting a polymorphism in a test sample containing a polymorphism site by optically measuring and analyzing a change of any kind of marker substance at a plurality of time points when the test sample is any kind of sample.

Applicants have canceled claims 1-26 without prejudice, rendering the rejection moot. New claims 27 to 30 are added, which are supported by the description provided in Examples 1 and 2 of the specification. No new matter is introduced by these new claims.

Applicants respectfully submit that new independent claim 27 defines the sample as a sample DNA. Applicants further submit that those skilled in the art are familiar with the choices of markers for labeling the probes to be used in the claimed methods of detection. Therefore, it would not take undue experimentation for those skilled in the art to make and use the detection methods as presently claimed. As such, withdrawal of the enablement rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

Claims 1-3, 21 and 24 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

It is respectfully submitted that the rejection is rendered moot in view of the cancellation of these claims. New claims 27-30 are not indefinite. Withdrawal of the rejection is therefore respectfully requested.

With respect to the §102(e) rejection based on Iris et al. and the §103 rejections based on Iris et al. in combination with other references, Applicants respectfully submit that the methods, as presently claimed, are not taught or suggested by Iris et al.

In the first instance, as presently claimed and as shown in FIG. 2 of the present application, the probe employed in the presently claimed method is labeled with a marker

substance at the nucleotide to be paired up with the nucleotide of the single-nucleotide substituted site. In contrast, according to Iris et al., as shown in FIG. 2, the probe is attached to a nucleotide at some distance away from the single-nucleotide replaced site. Unlike the present invention, the labeled nucleotide is not a nucleotide that pairs up with the nucleotide at the single-nucleotide replacement site. Further, according to Iris et al., the probe contains a first marker and a second marker, and additionally a peptide label to be trapped by an antibody chip. Thus, the presently claimed method and that of Iris et al. are distinct from each other with respect to the probe employed in the method.

Moreover, according to the presently claimed methods, the sample DNA and the probe are hybridized, as shown in FIG. 4 of the specification. Next, as a result of the hybridization, the part of the DNA that is double-stranded, is reacted with a nucleic acid synthesizing enzyme having a repair function. If there is a mismatch in the single-nucleotide replaced site, the mismatched part is cut by the enzyme. The cut nucleotide contains a marker substance that generates light of a wavelength assigned to the respective type of the nucleotide to identify a pattern of SNP. Afterwards, the micro-movement of the marker substance is optically measured at a plurality of points in a lapse of time. In contrast, the method of Iris et al. requires two types of markers for one type of nucleotide which may exist in the single nucleotide polymorphism at a site, as shown in FIG. 2 of this reference, and a peptide marker to bind to the antibody chip. The method of Iris et al. requires binding to the antibody chip first, then the cutting of the mismatch by an enzyme, and then binding again to the antibody chip.

It is apparent that the presently claimed methods are different from the method of Iris et al. Therefore, it is respectfully submitted that Iris et al. do not teach the presently claimed methods. As such, the rejection under §102(e) based on Iris et al. is overcome.

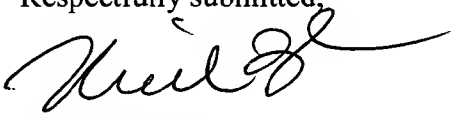
With respect to the §103 rejections based on Iris et al., Applicants respectfully submit that Iris et al. do not remotely suggest a technique similar to that employed by the presently claimed invention. The secondary reference, Palo et al., merely describes detection using a confocal microscope and the measurement of the variation in intensity of fluorescence in combination with a fluorescent correlation spectroscopy. The other secondary reference, Fujimiya et al., merely discloses a multi-colored electrophoretic pattern reading system. Neither of these secondary references cures the deficiencies of the primary reference.

Applicants further respectfully submit that the presently claimed methods are unobvious and have unexpected advantages, even if the techniques of Iris et al., Palo et al. and Fujimiya et al. were to be combined. In particular, with the methods of the present invention, it is possible to analyze a polymorphism quickly, simply and highly accurately without requiring a B/F separation, PCR or electrophoresis. Such a significantly advantageous effect has been achieved for the first time by the present invention and would not have been achieved simply by employing the techniques disclosed in Iris et al., Palo et al. and/or Fujimiya et al.

Accordingly, the §103 rejections based on Iris et al. in view of Palo et al., and on Iris et al. in view of Fujimiya et al., are overcome. Withdrawal of the rejections is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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PATENT OFFICE DATE STAMP WILL ACKNOWLEDGE RECEIPT OF:

1. General Transmittal (in dup)
2. Response To The Office Communication of May 3, 2005
3. Copies of Certified Japanese Priority Documents (3)
4. **HAND DELIVERY**

Applicants:	Kunio Hori, et al.
Serial No.:	09/995,100
Filed:	November 27, 2001
For:	METHOD FOR DETERMINING POLYMORPHISM
Docket:	15111
Dated:	May 31, 2005
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